ASHE *Regulatory Advisory*

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JCAHO Clarifies Their Expectations related to USP 797 in *Perspectives*

A Message to ASHE Members:

In the April 2006 edition of *Joint Commission Perspectives,* the Joint Commission (JCAHO) clarifies their expectations related to compliance with USP 797 in their article *Clarification: Joint Commission Expectations related to USP-NF Chapter 797 on Compounding Sterile Preparations.*

The article states: "**The Joint Commission will not survey for compliance with the details of USP 797**. How "exacting" the organization complies with the USP 797 guidelines and the suggested timeframes for compliance are based on organizational decision. An accredited organization can decide its compliance with USP 797 with advice from experts and stakeholders, such as the organization's director of pharmacy, risk manager, facility manager, microbiologist, infection control staff, and legal counsel, taking into account state laws and regulations. **If permitted by state laws, an organization may choose an alternative approach to a specific USP guideline based on review of literature or organizational studies**."

According to survey results released by the American Society of Health-System Pharmacists, Inc. in October 2005, the following states' Board of Pharmacy require compliance with USP 797: Arkansas, Indiana, Kansas, Louisiana, Maryland, Massachusetts, Nevada, North Carolina, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, Virginia, West Virginia, with more states pending decision.

JCAHO's clarification is intended to answer questions that have been raised from the previous April 2004 and October 2004 *Perspectives* articles on USP 797. It goes on to state: "The Joint Commission considers USP 797 a valuable set of guidelines — contemporary consensus-based safe practices — that describe a best practice for establishing safe processes in compounding sterile medications. USP 797 guidelines, while more specific than Joint Commission standards about sterile medication preparation and infection control, can help organizations comply with applicable Joint Commission standards". Specifically, it highlights Medication Management Standard MM.8.10, which requires "that organizations evaluate literature for new technologies and successful practices relevant to improving their medication management system".

ASHE members are encouraged to:

- **Obtain a copy of the entire article through their organization's JCAHO liaison** and to discuss with all stakeholders including pharmacy, risk management, microbiology, infection control, and legal counsel **before initiating construction or renovation of the existing pharmacy physical environment**.
- Contact your state Board of Pharmacy to determine the specific state requirements for design, construction, operation, and inspection/testing of pharmacy sterile compounding areas.
- Obtain a copy of the article: *I.V. admixture contamination rates: Traditional practice site versus a class 1000 cleanroom*, published Am J Health-Syst Pharm—Vol 62 Nov 15, 2005. This article compares the results of medications prepared in a clean room environment verse those prepared in a traditional pharmacy environment. The article states: "It cannot be assumed that the cleanroom environment and garb will prevent or reduce contamination. This false assumption could breed indifference in the personnel working within cleanrooms, thereby weakening their adherence to aseptic technique. This study demonstrates that when admixtures are prepared within a class 100 LAF hood, the operator becomes the most important variable affecting microbial contamination." And concludes that "The most important variable affecting microbial contamination of admixtures was the aseptic technique of personnel, not the environment in which the drugs were compounded."

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